PRVD2008-05

Proposed Re-evaluation Decision

Ethametsulfuron methyl

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Overview

Proposed Re-evaluation Decision for Ethametsulfuron Methyl

After a re-evaluation of the herbicide ethametsulfuron methyl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing ethametsulfuron methyl in Canada.

An evaluation of available scientific information found that products containing ethametsulfuron methyl have value in the food and crop industry and do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of ethametsulfuron methyl use on canola (spring seeded), condiment mustard (brown and oriental varieties) and sunflower, new risk reduction measures must be included on the labels of all ethametsulfuron methyl products. No additional data are being requested at this time.

The PMRA's pesticide re-evaluation program considers potential risks, as well as the value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

This proposal affects all end-use products containing ethametsulfuron methyl registered in Canada. Once the final re-evaluation decision is made, registrants will be instructed on how to address the new risk-reduction measures.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for ethametsulfuron methyl and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of ethametsulfuron methyl.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration[2]. The Act also requires that products have value[3] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous hazard and risk assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

Before making a re-evaluation decision on ethametsulfuron methyl, the PMRA will consider all comments received in response to this consultation document[4]. The PMRA will then publish a Re-evaluation Decision document[5] on ethametsulfuron methyl, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What is Ethametsulfuron Methyl?

Ethametsulfuron methyl is a selective systemic sulfonylurea herbicide. It is registered for postemergent use on canola (spring seeded), condiment mustard (brown and oriental varieties) and sunflower to control wild mustard and other broadleaf weeds. Ethametsulfuron methyl is to be applied once per year at a rate of 11.25 to 22.5 g a.i./ha by ground equipment only. The highest usage of ethametsulfuron methyl is on canola followed by mustard and sunflower.

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2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

3 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

4 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

5 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Ethametsulfuron Methyl Affect Human Health?

Ethametsulfuron methyl is unlikely to affect your health when used according to revised label directions.

Exposure to ethametsulfuron methyl may occur through diet (food and water), when handling treated crops, working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the dose levels where no health effects occur and the dose levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using ethametsulfuron methyl products according to label directions.

An acute overexposure to ethametsulfuron methyl may lead to mild eye irritation and/or developmental toxicity in animals and humans. Acute symptoms may include erythema, ocular and nasal discharge, slight to mild corneal opacity, light chemosis, or mild conjunctival redness. In females of childbearing age, overexposure may lead to increased early resorptions resulting in postimplantation loss. To prevent overexposure, label directions must be followed.

Additional toxic effects on body weight, the liver, lymph nodes, thyroid/parathyroid, and white blood cells were observed in animals at very high doses only and therefore would not likely occur when ethametsulfuron methyl products are used according to label directions. There was no evidence that ethametsulfuron methyl causes cancer in mice or rats which had been treated for most of their lifetime with ethametsulfuron methyl. Ethametsulfuron methyl did not cause mutations or damage to DNA in a number of laboratory tests. As a result, a cancer risk assessment is not required.

Although there are no risks of concern based on current uses of ethametsulfuron methyl, some additional protective measures have been proposed for inclusion on product labels to update the label to current standards.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to ethametsulfuron methyl was estimated from residues in treated crops and drinking water, including the most highly exposed subpopulation (e.g. children one to six years old). This aggregate exposure (i.e. to ethametsulfuron methyl from food and drinking water) represents less than 1% of the acute reference dose and less than 1% of the chronic reference dose.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Ethametsulfuron methyl is currently registered in Canada for use on canola (spring seeded), condiment mustard (brown and oriental varieties) and sunflower. MRLs for ethametsulfuron methyl are currently specified for canola and condiment mustard at 0.1 ppm, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. The proposed MRL amendments for ethametsulfuron methyl can be found in the Science Evaluation, Section 8.1.2 of this consultation document.

Risks in Residential and Other Non-Occupational Environments

Residential and other non-occupational risks are not of concern.

Ethametsulfuron methyl is not registered for use in any residential areas; therefore, no residential or other non-occupational risks are expected.

Occupational Risks From Handling Ethametsulfuron Methyl

Occupational risks are not of concern.

Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation, and considering the use of appropriate protective equipment, the risk estimates associated with mixing, loading and applying activities meet current standards for all use scenarios and are not of concern. The proposed personal protective equipment are long pants, long-sleeved shirt, socks, chemical-resistant gloves and footwear.

Occupational postapplication risks are not of concern.

Occupational postapplication risk assessments consider exposures to workers re-entering treated sites. Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation, and considering proposed protective measures (i.e. personal protective equipment, revised re-entry interval), the postapplication exposure risk estimate for re-entry workers performing high exposure activities (scouting) meet current standards and are not of concern.

Environmental Considerations

What Happens When Ethametsulfuron Methyl is Introduced Into the Environment?

Ethametsulfuron methyl poses a potential risk to terrestrial and aquatic plants, therefore additional risk reduction measures need to be observed.

When ethametsulfuron methyl is applied for control of weeds in crops, some of it finds its way into soil and water. The chemical is expected to be moderately persistent in soil as it is degraded by soil microbes. It is persistent in water. Both ethametsulfuron methyl and its breakdown products are mobile and hence can move freely in soil. However, field evidence indicates that ethametsulfuron methyl remains within the top 23 cm of the soil after application, and that its use would not result in significant groundwater contamination. Water runoff on the soil surface can also move ethametsulfuron methyl and its transformation products into nearby bodies of water such as ponds and rivers. Water monitoring of these bodies of water have revealed residues, but at concentrations below levels of concern for aquatic life. Several major products from the breakdown of ethametsulfuron methyl would be present in soil and aquatic systems, but most of them have not been fully characterized to estimate their fate in the environment.

When ethametsulfuron methyl is used for weed control in crops, there is a potential that sensitive plant species on land and in water may be exposed to the chemical as a result of the spray drifting or runoff. Some of these species are sensitive to the chemical and would be adversely affected. To minimize the potential exposure, strips of land (buffer zones) between the agricultural field and the non target terrestrial or aquatic areas will be left

unsprayed. The width of these buffer zones will be specified on the product label. Ethametsulfuron methyl presents negligible risk to wild birds, mammals, bees, earthworms, fish, amphibians, aquatic invertebrates, and algae because concentrations in the environments are expected to be at levels that are not harmful.

Value Considerations

What is the Value of Ethametsulfuron Methyl?

Ethametsulfuron methyl controls wild mustard and other broadleaf weeds in several crops at a low application rate.

Ethametsulfuron methyl contributes to the reduction of the economic losses caused by weeds estimated at a total of $87.2 million in the early 1990s for canola, mustard and sunflower. Ethametsulfuron methyl is the only selective postemergent herbicide for the control of wild mustard in conventional canola and condiment mustard (brown and oriental). Ethametsulfuron methyl is the only alternative postemergent broadleaf herbicide for use on sunflower. Although ethametsulfuron methyl plays a role in mitigating resistance development in weeds to other herbicide groups, resistance management must be considered as more weed species are reported to be resistant to herbicides that inhibit acetolactate synthase (such as ethametsulfuron methyl) than to herbicides having other modes of action.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of ethametsulfuron methyl, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- To protect mixer/loader/applicators: additional protective equipment
- To protect workers re-entering treated sites: a restricted-entry interval
- To protect workers using wettable granular formulation: additional precautionary statements and directions for use
- To avoid drift to areas of human habitation or areas of human activity: precautionary statements

Environment

- To protect non-target terrestrial and aquatic plants: adding precautionary statements and directions for use, as well as, buffer zones for terrestrial and aquatic plants
- To reduce the potential runoff of ethametsulfuron methyl to adjacent aquatic habitats: cautionary statements for use on sites with characteristics that may be conducive to runoff when heavy rain is forecasted

Next Steps

Before making a re-evaluation decision on ethametsulfuron methyl, the PMRA will consider all comments received in response to this consultation document. The PMRA will then publish a Re-evaluation Decision document, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Other Information

When the re-evaluation decision is made, the PMRA will publish an Evaluation Report on ethametsulfuron methyl in the context of this re-evaluation decision (based on the Science Evaluation of this consultation document). In addition, the test data on which the decision is based will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

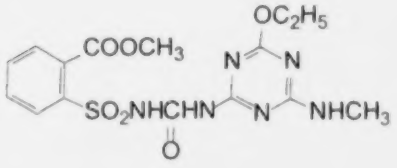
1.0 Introduction

Ethametsulfuron methyl is a selective systemic herbicide. It belongs to the sulfonylurea chemical family and is classified as a Group 2 herbicide. The herbicidal activity of ethametsulfuron methyl is due to the inhibition of the plant enzyme acetolactate synthase (ALS), also called acetohydroxyacid synthase (AHAS).

Following the re-evaluation announcement for ethametsulfuron methyl, E.I. du Pont Canada Company, the registrant of the technical grade active ingredient (TGAI) and primary data provider in Canada, indicated it would continue to support all uses included on the labels of the Commercial Class end-use products. There are no Domestic Class products containing ethametsulfuron methyl registered in Canada.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Ethametsulfuron methyl
Function	Herbicide
Chemical family	Sulfonylurea
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Methyl 2-[(4-ethoxyl-6-methylamino-1,3,5-triazin-2-yl)carbamoylsulfamoyl]benzoate
2. Chemical Abstracts Service (CAS)	Methyl 2-[[[[[4-ethoxy-6-(methylamino)-1,3,5-triazin-2-yl] amino]carbonyl]amino]sulfonyl]benzoate
CAS Registry Number	97780-06-8
Molecular formula	$C_{15}H_{18}N_6O_6S$
Molecular weight	410.4
Structural formula	

PCP Registration Number	21554
Purity	98.7% NS (limits: 96–100%)
Basic Manufacturer	DuPont de Nemours (Flandre) S.A. Usine De Loon Plage Route Du Pres Fevrier Loon Plage, France

Identity of relevant impurities of human health or environmental concern:

Based on the manufacturing process and the raw materials used, the product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	7.73×10^{-10} mPa
Henry's law constant	6.34×10^{-12} Pa m^3 mol^{-1}
Ultraviolet (UV)/visible spectrum	λ_{max} (in acetonitrile) = 220 nm. No absorption at wavelength > 300 nm
Solubility in water at 20°C	pH — solubility (mg/L) 5 — 1.7 7 — 50 9 — 410
n-Octanol–water partition coefficient (log K_{ow})	pH — log K_{ow} 7 — 0.89 5 — 1.588
Dissociation constant (pKa)	pKa = 4.6

2.3 Description of Registered Ethametsulfuron Methyl Uses

Appendix I lists all ethametsulfuron methyl products registered under the authority of the *Pest Control Products Act*, specifically including one technical grade active ingredient, one manufacturing concentrate and two Commercial Class end-use products.

Appendix II lists all the uses for which ethametsulfuron methyl is presently registered. All uses were supported by the registrant at the start of the re-evaluation and were, therefore, considered in the health and environmental risk assessments. Also presented is whether the uses were added through the PMRA minor use program. While currently supported by the registrant, the data supporting these minor uses were originally generated by a user group.

Uses of ethametsulfuron methyl belong to the following use site categories: terrestrial food crops, terrestrial feed crops and industrial oilseed and fibre crops. The crops specifically include canola (spring seeded), condiment mustard (brown and oriental varieties) and sunflower.

3.0 Impact on Human and Animal Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to the effects of a chemical than the most sensitive animal species. The health effects noted here were observed in animals at dose levels at least 100-fold (often much higher) above levels to which humans are normally exposed through use of products containing this chemical.

3.1 Toxicology Summary

The toxicology database supporting ethametsulfuron methyl (DPX-A7881) is primarily based on studies from the technical registrant. In laboratory animals, ethametsulfuron methyl was of low acute toxicity by the oral, dermal, and inhalation routes of exposure, non-irritating to rabbit skin, mildly irritating to rabbit eyes, and non-sensitizing in Guinea pigs.

With oral exposure, ethametsulfuron methyl was mostly excreted in urine and feces (50/50) within 72 hours of dosing, and over half of the administered dose was excreted unchanged in the urine and feces. Accumulation within tissues was minimal. Urine and fecal extracts revealed the identity of two major metabolites (N-dimethyl and O-deethyl DPX-A7881). The predominant route of metabolism for low dose exposure lead to N-dimethyl DPX-A7881 and for high dose exposure to O-deethyl DPX-A7881. A unique plant metabolite, o-deethyl-n-dimethyl DPX-A7881, was identified in very low quantities (<50 ppb) in the canola metabolism study. This finding is unlikely to be of concern due to the very small amounts detected. Furthermore, structurally, this plant metabolite is similar to the other metabolites which were detected in mammals. Therefore, o-deethyl-n-dimethyl DPX-A7881 is expected to have a similar toxicological profile to the latter, and its potential toxicity is considered to be covered under the testing of the parent compound.

In subchronic oral toxicity studies in mice, rats, and dogs, ethametsulfuron methyl exerted minimal toxicity and lowest observed adverse effect levels (LOAELs) were not established for any of the 90-day studies. Repeat-dose inhalation and dermal studies were not available, however, a study waiver for the latter was considered acceptable. Although no data or study waiver were submitted to fulfill the requirement for a repeat-dose inhalation study, based on the overall low toxicity profile of ethametsulfuron methyl, the lack of specific lung pathology, and the low acute toxicity observed by inhalation, this data gap will not impact the current risk assessment.

Body-weight effects were the most common and sensitive endpoint in long-term studies as well as in the one-year dog study and two-generation rat reproduction study. Ethametsulfuron methyl was not oncogenic in mice or rats, and all genotoxicity studies were negative. Reproductive and offspring sensitivities were not observed.

In rabbits, developmental toxicity was evident at lower doses than in rats after oral exposure to ethametsulfuron methyl. At the lowest dose tested, increased early resorptions and postimplantation loss with a corresponding decreased number of live fetuses per litter were noted. Thus, in rabbits, oral exposure to ethametsulfuron methyl during gestation resulted in severe effects (increased early resorptions, increased postimplantation loss, and decreased number of live fetuses per litter). Maternal and developmental no observed adverse effect levels (NOAELs) were not determined for this study.

Reference doses have been set based on NOAELs or LOAELs for the most sensitive indicators of toxicity, namely body-weight effects in rats and developmental toxicity observed in rabbits. These reference doses incorporate uncertainty factors to account for extrapolating between laboratory animals and humans and for variability within the human population as well as for the use of a LOAEL instead of a NOAEL where necessary. Consistent with past PMRA policy and now formalized under the new *Pest Control Products Act* that recently came into force, additional safety factors have also been applied, where warranted, to protect children and pregnant females from relevant endpoints of concern or any database uncertainty regarding a potential for increased severity of effect in these population subgroups.

The toxicology profile of ethametsulfuron methyl toxicology endpoints used in the risk assessment of ethametsulfuron methyl are summarized in Appendix III and IV.

3.2 Occupational and Non-occupational Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant NOAEL from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE which incorporates safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects. However, MOEs less than the target MOE require mitigation measures to reduce risk.

3.2.1 Toxicological Endpoints

To estimate risk for short-term (< 30 days) dermal and inhalation exposure for females of childbearing age (13–49 years), an oral LOAEL of 250 mg/kg bw/day from a repeat-dose rabbit developmental toxicity study was used in which increased early resorptions and postimplantation loss, and decreased number of live fetuses per litter were observed. The target MOE selected when using this study is 1000, accounting for standard uncertainty factors of 10 for interspecies extrapolation and 10 for intraspecies variability as well as a threefold safety factor for the use of a LOAEL instead of a NOAEL and another threefold safety factor for the observed severity of effect in pregnant animals. This endpoint is considered protective of all subpopulations including infants, children, and females of childbearing age.

To estimate the risk from short-term (< 30 days) dermal and inhalation exposures for the general population, a NOAEL of 395 mg/kg bw/day based on body-weight and liver effects from a two-generation rat reproduction study, was selected. The target MOE selected when using this study is 100, accounting for standard uncertainty factors of 10 for interspecies extrapolation and 10 for intraspecies variability.

Dermal Absorption
The PMRA can estimate dermal absorption by considering physical and chemical properties of a substance (e.g. molecular weight, log K_{ow} and solubility) and/or by considering chemical-specific dermal absorption data (e.g. in vivo rat dermal absorption study). Based on a first tier risk assessment, a default dermal absorption factor of 100% was used. No chemical specific dermal absorption data were available for the estimation of dermal absorption.

3.2.2 Occupational Exposure and Risk

Workers can be exposed to ethametsulfuron methyl through mixing, loading and/or applying the pesticide, and when re-entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.2.2.1 Mixer/Loader/Applicator Exposure and Risk

There are potential exposures to mixers, loaders, applicators and other handlers. The following major exposure scenarios were assessed :

- Mixing and loading wettable granules.
- Mixing and loading wettable granules in water-soluble package (WSP).
- Applying by groundboom sprayer.

Occupational handlers of ethametsulfuron methyl include farmers and custom agricultural applicators who mix, load and apply the herbicide. One application is permitted per season and based on the timing of application, the duration of exposure for farmers and custom applicators is expected to be short-term (1–30 days).

Exposure for all crop scenarios is predominantly dermal, with inhalation accounting for a minor component of overall exposure. The toxicological endpoint for these scenarios is based on an oral LOAEL from a rabbit developmental toxicity study. Because no dermal absorption study was available, the PMRA will use a dermal absorption factor of 100 % as a part of a first tier exposure risk assessment.

The PMRA estimated handler exposure based on the following level of personal protective equipment (PPE) :

Baseline PPE : Long pants, long-sleeved shirt and chemical-resistant gloves (gloves not required for groundboom sprayers).

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment might be refined with product-specific exposure data, biological monitoring data, and/or dermal absorption data.

No chemical specific exposure studies were available for use in the re-evaluation of ethametsulfuron methyl. Thus, appropriate dermal and inhalation exposures were estimated using the Pesticide Handlers Exposure Database (PHED), Version 1.1. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of personal protective equipment.

In some cases, PHED did not contain appropriate data sets to estimate exposure to workers wearing additional PPE and/or using engineering controls, thus protection factors are applied for specific PPE and/or engineering controls. Surrogate data for wettable granules in WSP were not available in PHED, therefore closed mixing and loading data for wettable granules were used.

PHED unit exposures coupled with information on the amount of ethametsulfuron methyl handled per day was used to estimate handler exposure. The amount handled per day is based upon the maximum label application rate and default assumptions on the area (of crop) which can reasonably be treated in one day.

Calculated MOEs exceed the target MOE for all exposure scenarios and are summarized in Appendix V, Table 1.

3.2.2.2 Postapplication Worker Exposure and Risk

Workers who re-enter treated sites to conduct activities involving foliar contact may be exposed to ethametsulfuron methyl. Based on the crops and their associated re-entry activities, exposure to ethametsulfuron methyl is expected to be short-term (1 to 30 days) in duration. One application per crop per season is expected (as per product labels) and post-application exposure is from scouting.

Default dislodgeable foliar residue (DFR) values and activity specific transfer coefficients (TC) were used to estimate postapplication exposure resulting from contact with treated foliage at various times after application. DFR data represent the amount of residue that can be dislodged or transferred from a treated surface, such as the leaves of a plant. In this case, no DFR studies were submitted, therefore, a default peak DFR value of 20% of the application rate with 10% dissipation per day was used. A TC represents the amount of foliar contact per unit time and relates worker exposure to dislodgeable residues. TCs are specific to a given crop and activity combination (e.g. hand harvesting apples, scouting late season cotton) and reflect standard agricultural work clothing worn by adult workers.

The postapplication exposure risk estimates include a number of conservative inputs, such as the assumption that workers are exposed to residues following the maximum number of applications at the maximum rate.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before one can safely re-enter. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in MOEs above the target MOE. Calculated MOEs exceed the target MOE on day 0, and proposed REIs are set at 12 hours. Results of the postapplication exposure risk assessment for each potential use scenario are summarized in Appendix V, Table 2.

3.2.3 Non-occupational Exposure and Risk

3.2.3.1 Residential Handler and Risk

There are no domestic class products registered for ethametsulfuron methyl in Canada; therefore, a residential handler risk assessment was not required.

3.2.3.2 Bystander Exposure and Risk

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible, thus, a bystander exposure risk assessment was not required.

3.3 Dietary Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to ethametsulfuron methyl from treated imports is also included in the assessment. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when risk exceeds 100% of the reference dose. The PMRA's Science Policy Notice SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed acute and chronic risk assessments procedures.

Residue estimates used in the dietary risk assessment (DRA) may be conservatively based on the maximum residue limits (MRL) or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency's National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (PDP).

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.03), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendix VI and VII.

3.3.1 Determination of Acute Reference Dose

An acute (one-day) reference dose (ARfD) for the general population was not calculated since there was not an acute endpoint of concern. However, an ArfD for the population subgroup females of child-bearing age (13–49 years of age) was derived from a developmental toxicity study in rabbits that had a LOAEL of 250 mg/kg bw based on increased early resorptions and postimplantation loss, and a decreased number of live fetuses per litter. An overall uncertainty factor of 1000 was required to account for interspecies extrapolation (tenfold), intraspecies variability (10-fold), as well as the use of a LOAEL instead of a NOAEL (threefold) and the observed severity of effect (threefold), resulting in an ARfD of 0.25 mg/kg bw (250 mg/kg bw ÷ 1000). This endpoint is considered protective of all subpopulations including infants, children, and females of childbearing age (13–49 years).

3.3.2 Acute Dietary Exposure and Risk Assessment

Acute dietary risk is calculated considering the highest ingestion of ethametsulfuron methyl that would be likely on any one day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of ethametsulfuron methyl residue that might be consumed in a day. When the expected intake of residues is less than the ARfD, then acute dietary exposure is considered to be acceptable.

The acute potential daily intake accounted for less than 1% of all the female subpopulations and is, therefore, not of concern.

3.3.3 Determination of Acceptable Daily Intake

The acceptable daily intake (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects, that was selected was based on a NOAEL of 26 mg/kg bw/day from a two-year combined chronic toxicity and carcinogenicity study in rats. The endpoint selected was based on decreased body weight and body-weight gain in females at a LOAEL of 267 mg/kg bw/day. An overall uncertainty factor of 100 was required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold), resulting in an ADI of 0.26 mg/kg bw/day (26 mg/kg bw/day ÷ 100). Although the ADI is slightly larger than the ARfD, the values are close and the difference between them should not impact the risk assessment. In addition, the selected ADI has an inherent 962-fold safety factor to the LOAEL of the rabbit developmental toxicity study and is thus protective of the severity of effect noted in the latter. This endpoint is considered protective of all subpopulations including infants, children, and females of childbearing age (13–49 years).

3.3.4 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated by using the average consumption of different foods and the average residue values on those foods. This expected intake of residues was then compared to the ADI. When the expected intake of residues is less than the ADI, then chronic dietary exposure is acceptable.

The chronic potential daily intake accounted for less than 1% of the ADI for all subpopulations and is, therefore, not of concern.

3.3.5 Cancer Potency Factor

A cancer risk assessment was not conducted since the ethametsulfuron methyl database did not suggest any carcinogenic potential in mice or rats.

3.4 Exposure From Drinking Water

3.4.1 Concentrations in Drinking Water

Ethametsufuron methyl residues in potential drinking water sources were estimated using computer simulation models. The acute and the chronic estimated drinking water concentration values used in the exposure model are 3.6 ppb and 3.3 ppb, respectively.

3.4.2 Drinking Water Exposure and Risk Assessment

Drinking water estimates were incorporated directly in the exposure model. For more information, please refer to the aggregate risk assessment (Section 3.5).

3.5 Aggregate Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

As residential use of ethametsulfuron methyl is not permitted, aggregate exposure is from dietary and drinking water exposures only (see Section 3.3 and 3.4). Acute and chronic aggregate (food and water) exposures were less than the respective reference doses. Therefore, aggregate exposure from all relevant sources is not considered a health concern.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Based on its physical-chemical properties (Section 2.2), ethametsulfuron methyl is very soluble in water, has a very low potential for volatilization from moist soils or water surfaces under field conditions, and is not likely to bioaccumulate in organisms. Environmental fate data for ethametsulfuron methyl are summarized in Appendix X, Table 1. Ethametsulfuron methyl is stable to hydrolysis at neutral and alkaline pH and phototransformation is a slow process in water and soils. They are not important routes of transformation of ethametsulfuron methyl in the environment.

Ethametsulfuron methyl is persistent to moderately persistent in soil under aerobic conditions. The rate of aerobic soil biotransformation is dependent upon temperature, pH and moisture content. Warmer and moister soils tend to degrade ethametsulfuron methyl more rapidly than dryer soil. Major transformation products are triazine amine and saccharin. Field dissipation studies resulted in half-lives similar to those determined in laboratory studies, with values ranging from 30–161 days. Accumulation in soils is unlikely.

In the aquatic environment, ethametsulfuron methyl is persistent as aerobic and anaerobic aquatic biotransformation processes are slow. Triazine amine, D-demethyl and saccharin are the major transformation products. Ethametsulfuron methyl is expected to be moderately persistent in sediments of acidic pH in view of hydrolysis.

Ethametsulfuron methyl does not bind strongly to soil and sediment but rather partitions mainly to aqueous phase. Laboratory studies on adsorption/desorption and soil column leaching studies indicate that ethametsulfuron methyl and the major transformation product saccharin have a potential to be mobile, although TLC studies suggest ethametsulfuron methyl may demonstrate only slight mobility. In terrestrial field studies conducted in Canada and in the United States, varying degrees of leaching have been identified. The extent of ethametsulfuron methyl leaching is related to the time of application, amount of rainfall and soil characteristics. The potential for leaching is prominent in non-acidic soils because of increased solubility and decreased adsorption. The field dissipation studies showed no leaching beyond 23 cm depth.

No information is available concerning the leaching potential of ethametsulfuron methyl transformation products under field conditions. Canadian water monitoring data show detection of ethametsulfuron methyl in surface water with concentrations ranging from 0.3 to 80.42 ng/L (Appendix VII). At present, there are no monitoring data for groundwater.

4.2 Effects on Non-Target Species

The environmental risk assessment determines the potential for adverse ecological effects in each environmental compartment by comparing the ratio of the estimated environmental exposure to the ecotoxicological effect. The estimated environmental exposure concentration (EEC) is the initial or cumulative concentration of pesticide in the various sources of food, water and soil to which the organism is exposed. EECs are calculated by different methods for each media (food, water or soil). If multiple applications of pesticide are used, cumulative EECs are determined by using the time taken to decline to 50% of the original application (DT_{50}) using the minimum time interval between applications for each environmental media.

The risk assessment is initially conducted using a screening-level scenario which assumes maximum exposure (EEC) and the most sensitive toxicological endpoint for the organism of interest. This assumes direct application to the environmental media (food, water, soil) to which the organism is exposed. This is the most conservative scenario and generally does not reflect the exposure to which an organism would be subject when the pesticide is applied according to the label instructions. Risk to the environment is calculated as a risk quotient (RQ) which is the ratio between the environmental exposure and the toxicological endpoint for the organism (i.e. RQ = EEC/toxicological endpoint). The threshold or level of concern for potentially harmful effects to an organism is an RQ value of 1 where the exposure exactly equals the toxicological endpoint. RQ values greater than or equal to 1 are considered to equal or exceed the level of concern which may result in potentially harmful effects to the organism. RQ values less than 1 indicate negligible risk to the organism because they are below the threshold for harmful effects. In the latter case, no further assessment is carried out. If the RQ is greater than or equal to 1, the level of concern, then a refinement of the risk assessment is carried out to assess the level of concern using scenarios which are a better approximation of exposure or toxicological effects and less conservative. Refinements can include (i) exposure from the fraction of pesticide which drifts onto non target habitats, instead of assuming 100% overspray, and (ii) exposure from the amount of pesticide predicted in runoff, instead of assuming direct overspray to water (i.e. 100% exposure). The refinements may also consider different toxicity endpoints or a percentile of a species sensitivity distribution rather than the most sensitive endpoint. They may also consider the results of a mesocosm study using several species rather than the toxicity from a single species. Further refinements to the risk assessment may consider the use of monitoring data collected in the field rather than EECs generated by a model.

4.2.1 Effects on Terrestrial Organisms

A risk assessment of ethametsulfuron methyl to terrestrial organisms was based upon an evaluation of toxicity data of ethametsulfuron methyl to earthworms (acute contact), bees (acute oral and contact), two species of birds (acute oral, dietary, and chronic), four species of mammals (acute oral, and chronic), and close to 50 species of terrestrial plants (seedling emergence and vegetative vigour). A summary of terrestrial toxicity data for ethametsulfuron methyl is presented in Appendix X, Table 2. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with ethametsulfuron methyl.

For birds and mammals, the lowest toxicity endpoints (acute oral, dietary and reproduction) were used to extrapolate toxicity endpoints for birds and mammals of different sizes (20, 100 and 1000 g for birds and 15, 35 and 1000 g for mammals). To address differences in species sensitivity, the acute oral LD_{50} and dietary LC_{50}, converted to daily dose, was further divided by a safety factor of 10. The screening level assessment used relevant food categories representing specific feeding guilds for each bird and mammal size class consisting of 100% of a particular dietary item (plants, grain/seeds, insects and fruit). Estimated dietary exposures (EDE) for each bird and mammal size were calculated based on EECs for each feeding preference group at each application rate and food ingestion rates. As no small birds in North America are known to eat a diet primarily of leafy plant material or grass, EDEs for small birds (20 and 100g) based on a 100% diet of plants were not calculated.

Ethametsulfuron methyl demonstrated no adverse toxicological effects on terrestrial invertebrates, birds or mammals on an acute oral, dietary and reproductive basis. As ethametsulfuron methyl is a herbicide, adverse effects to non-target terrestrial plants are expected. Vegetative vigour studies indicated that, although many plant species grew successfully, some species did not follow normal growth patterns and that detrimental effects (failure to recover) were observed at very low rates of application. The effects are likely due to the ability of ethametsulfuron methyl to inhibit the plant enzyme acetolactate synthase, stopping cell division and plant growth by blocking branched chain amino acid biosynthesis. No toxicity studies conducted with ethametsulfuron methyl transformation products were available for review.

The screening level risk assessment indicated that exposure to ethametsulfuron methyl does not pose a risk to terrestrial invertebrates, mammals and birds. Appendix X, Tables 3 and 4 summarize the risk assessment from ethametsulfuron methyl to terrestrial organisms.

The ethametsulfuron methyl herbicide poses a risk to non target terrestrial plants. The level of concern (LOC) was exceeded by 1389 times at the lowest application rate (12.5 g a.i./ha). Less than 0.072% of the ethametsulfuron methyl application rate (12.5–22.5 g a.i./ha) is expected to negatively affect non-target terrestrial plants (EC_{25} divided by the application rate). As a result, a refinement of the risk assessment was conducted taking into consideration the concentrations of ethametsulfuron methyl that could be present in terrestrial habitat directly adjacent to the application field through spray drift. Spray drift data for a medium ASAE droplet size, as is

generally used in ground boom applications of herbicides, indicate that the maximum amount of spray that will drift one metre down wind from the point of application during spraying is 6%. Using this percent drift, the off-site EECs for ethametsulfuron methyl were calculated. Based on this method of refinement, ethametsulfuron methyl poses a reduced risk to non-target terrestrial plants directly adjacent to the application field. Exceedance of the LOC was reduced to 83 times from 1389 times for the lowest application rate. Buffer zones will be required to mitigate the risk of ethametsulfuron methyl to non-target terrestrial plants. Appendix X, Table 5 summarizes the refined risk assessment of ethametsulfuron methyl to non-target terrestrial plants.

4.2.2 Effects on Aquatic Organisms

Risk to aquatic organisms, acute and chronic, is based on an evaluation of toxicity data on ethametsulfuron methyl for seven freshwater species (one invertebrate, two fish, one alga, and three vascular plants). Some toxicity data on the transformation products were also available. A summary of aquatic toxicity data for ethametsulfuron methyl and its transformation products is presented in Appendix X, Table 2. For the risk assessment, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with ethametsulfuron methyl. The endpoints were derived by dividing the EC_{50} or LC_{50} from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates and plants, and by a factor of 10 for fish and amphibians (based on surrogate data from fish studies).

Ethametsulfuron methyl and its transformation products, including triazine amine, are of negligible risk to freshwater invertebrates based on acute and chronic toxicity and to fish on an acute basis. Data on chronic effects on freshwater fish were not available. No chronic toxicity data were available for estuarine/marine species. As ethametsulfuron methyl is a herbicide, adverse effects to non-target aquatic plants are expected. Ethametsulfuron methyl significantly affected frond numbers of duckweed and root dry weight of sago pondweed. The effect on the algal species tested was limited. No toxicity studies conducted with ethametsulfuron methyl transformation products on vascular plants and algae were available for review.

The risk assessment was conducted using data for the most sensitive freshwater organisms tested *Daphnia magna*, bluegill sunfish (*Lepomis macrochirus*) and rainbow trout (*Oncorhynchus mykiss*), algae (*Selenastrum capricornutum*) and aquatic plant (*Potamogeton pectinatus)*.

The screening level risk assessment indicated that ethametsulfuron methyl does not pose a risk to freshwater invertebrates, fish, amphibians and algae. However, a potential risk to vascular plants was identified at the lowest application rate. The LOC was exceeded by 64 times at the application rate of 12.5 g a.i./ha. Thus, a refined risk assessment was triggered and which reduced the exceedance of the LOC at the lowest application rate to 3.6 times from spray drift and to 2.3 from runoff. Water monitoring data were not used in the environmental risk assessment because it likely underestimated the peak exposure of ethametsulfuron methyl due to many sources of uncertainty (see Appendix VIII for more explanation).

Risk assessment from the transformation product triazine amine was also conducted assuming that EEC for transformation products is the same as for the parent ethametsulfuron methyl with a correction for molecular weight. The potential risk of triazine amine to *Daphnia magna* was negligible. Appendix X, Tables 6 and 7 summarize risk assessment from ethametsulfuron methyl and its transformation products to aquatic organisms. Appendix X, Tables 8 and 9 summarize refined risk to aquatic plants from ethametsulfuron methyl spray drift and runoff, respectively.

5.0 Value

5.1 Commercial Class Products

All ethametsulfuron methyl uses are supported by the registrant. There are no risk concerns for any of the registered uses. Consequently, no alternatives to the use of ethametsulfuron methyl were considered.

5.2 Domestic Class Products

There are no Domestic Class products containing ethametsulfuron methyl registered in Canada.

5.3 Value of Ethametsulfuron Methyl

Wild mustard is an economically important weed for producers of conventional canola and condiment mustard (brown and oriental varieties). Wild mustard not only reduces crop yields but also is a serious contaminant of canola and mustard seeds. Wild mustard seed is similar in size and shape to canola and mustard seeds, making separation impossible by conventional methods. Wild mustard seed contamination in canola and mustard leads to downgrading of quality, has implications for the crushing industry and contributes to the spread of weed infestation. Several herbicides can be used to control wild mustard in herbicide-tolerant canola. However, ethametsulfuron methyl is the only selective postemergent herbicide for the control of wild mustard in conventional canola and mustard. Ethametsulfuron methyl is the only alternative postemergent broadleaf herbicide for use on sunflower.

In Canada, the estimated average annual losses caused by weeds (in the early 1990s) were $80.4 million in canola, $4.7 million in mustard (all types) and $2.1 million in sunflower. Ethametsulfuron methyl was reported to be used in these crops to prevent and reduce a portion of the economic losses caused by weeds.

The development of herbicide resistance in weeds associated with the use of ethametsulfuron methyl must be considered. Due to the widespread and frequent use of ALS inhibiting (Group 2) herbicides such as ethametsulfuron methyl; and lack of rotation with herbicides with other modes of action, more resistant weed biotypes have been documented in Canada with Group 2 herbicides than with any other herbicide group, including 12 broadleaf weeds (cleavers, chickweed, hemp-nettle, kochia, lamb's-quarters, giant ragweed, ball mustard, wild mustard, redroot pigweed, Russian thistle, spiny annual sowthistle, and stinkweed) and two grassy weeds (green foxtail and wild oats).

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy (TSMP), a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, ethametsulfuron methyl was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of ethametsulfuron methyl were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use products. The PMRA has reached the following conclusions:

- The log *n*-octanol–water partition coefficient (log K_{ow}) of ethametsulfuron methyl ranges from 0.05 to 1.6, which is below the TSMP Track 1 cut-off criterion for log $K_{ow} \geq 5.0$. Ethametsulfuron methyl meets the criterion for persistence in water as its half-life values in water (272 days), is above the TSMP Track 1 cut-off criterion for water (≥182 days). However, ethametsulfuron methyl does not meet the criterion for persistence in soil; the half-life determined for ethametsulfuron methyl in soil (63 days*) is below the TSMP Track 1 cut-off for sediment (≥182 days) and soil (≥182 days). The vapour pressure and Henry's law constant indicate that ethametsulfuron methyl will not volatilize from water or moist soil under field conditions, thus long-range atmospheric transport of ethametsulfuron methyl is not likely to occur.

Therefore, the use of ethametsulfuron methyl is not expected to result in the entry of Track 1 substances into the environment.

6.1 Formulant Issues

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulant Policy and Implementation Guidance Document*, published on 31 May 2006.

7.0 Summary

7.1 Human Health and Safety

7.1.1 Occupational Risk

Risk estimates associated with mixing, loading and applying ethametsulfuron methyl for proposed label uses are not of concern provided the recommended personal protective equipment is used. Postapplication exposure risks to re-entry workers are also not of concern provided the precautions and directions for use are followed.

7.1.2 Dietary Risk from Food and Water

The aggregate acute and chronic dietary (food and water) risk assessments demonstrate that there were no dietary concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. In addition, no dietary concerns were evident for nursing or pregnant females or based on gender in general.

7.1.3 Residential Risk

There are no domestic uses of ethametsulfuron methyl. Risks to homeowners from contact with commercially treated plants do not pose a health concern.

7.2 Environmental Risk

Ethametsulfuron methyl is moderately persistent to persistent in most soils and persistent in aquatic systems. Ethametsulfuron methyl is mobile and may occur in runoff and surface waters at very low concentrations. A screening level risk assessment indicates that it is not a risk to terrestrial and aquatic organisms, except for plants. A refined risk assessments for non-target terrestrial and aquatic plants indicates that spray drift will have adverse effects on non-target plants. The risk quotients in the refined assessments of non-target terrestrial and aquatic plants exceeded the level of concern (LOC) by a factor of 83 and 4, respectively (RQs greater than 1).

7.3 Value

From the value perspective, ethametsulfuron methyl is acceptable for continued registration.

8.0 Proposed Re-evaluation Decision

The PMRA is proposing that ethametsulfuron methyl is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and environment. As a condition of the continued registration of ethametsulfuron methyl uses, new risk reduction measures must be included on the labels of all products. No additional data are being requested at this time.

8.1 Proposed Regulatory Action Related to Human Health

The PMRA has determined that the dietary and drinking water risks as well as worker risks during mixing, loading and application are acceptable for all uses, provided the mitigation measures listed in Appendix XI are implemented.

8.1.1 Residue Definition for Risk Assessment and Enforcement

Division 15, Table II, of the Food and Drug Regulations has no specified MRLs or residue definition for ethametsulfuron methyl. However, in PMRL2006-01 the residue definition is proposed as: methyl 2-[[[[[4-ethoxy-6-(methylamino)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]benzoate. This residue definition is consistent with that of the United States Environmental Protection Agency (USEPA).

8.1.2 Maximum Residue Limits for Ethametsulfuron Methyl in Food

In general, when the re-evaluation of a pesticide is complete, the PMRA intends to update Canadian maximum residue limits and to remove MRLs that are no longer supported.

As indicated in Table 8.1.2, residues of ethametsulfuron methyl in mustard seed, rapeseed (canola) and sunflower seeds approved for treatment in Canada without a specified MRL, must not exceed the general MRL of 0.1 ppm.

Where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues not exceed 0.1 ppm, considered a general MRL for enforcement purposes. Currently, residues of ethametsulfuron methyl in all agricultural commodities including mustard seed, rapeseed (canola) and sunflower seeds approved for treatment in Canada are regulated by subsection B.15.002(1). However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

Extrapolation of available residue data following good agricultural practices (GAP), as described by the current product labels, indicated that residues would not exceed the limit of quantitation of the analytical method of 0.05 ppm for mustard seed and 0.02 ppm for rapeseed (canola) and sunflower seeds.

Table 8.1.2 Ethametsulfuron Methyl MRLs for Commodities Approved in Canada

Commodity	MRL (ppm)
Mustard seed	0.05
Rapeseed (canola)	0.02
Sunflower seeds	0.02

8.2 Proposed Regulatory Action Related to Environment

The risk assessment has indicated that adverse effects on non-target terrestrial and aquatic plants are expected. To reduce the effects of ethametsulfuron methyl in the environment, mitigation in the form of precautionary label statements and buffer zones are required. Environmental mitigation statements and buffer zones are listed in Appendix XI.

List of Abbreviations

a.i.	active ingredient
ADI	acceptable daily intake
AHAS	acetohydroxyacid synthase
ALS	acetolactate synthase
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmospheres
bw	body weight
CFIA	Canadian Food Inspection Agency
cm	centimetre(s)
DEEM®	Dietary Exposure Evaluation Model
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DT_{50}	dissipation time to 50% (the dose required to observe a 50% decline in the test population)
DWLOC	drinking water level of comparison
EC_{25}	exposure concentration to 25% (a concentration causing 25% adverse effects in the test population
EC_{50}	exposure concentration to 50% (a concentration causing 50% adverse effects in the test population
EChE	erythrocyte cholinesterase
EEC	expected environmental concentration
EXAMS	Exposure Analysis Modeling System
F_0	parental animals
F_1	first filial generation
g	gram(s)
GAP	good agricultural practice
GC-FPD	Gas Chromatography-Flame Photometric Detector
GC-MSD	Gas Chromatography-Mass Selective detector
GC-NPD	Gas Chromatography-Nitrogen Phosphorous Detector
h	hour(s)
ha	hectare(s)
Hg	mercury
IRED	Interim Reregistration Eligibility Decision (USEPA Document)
K_d	adsorption coefficient
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50% (a concentration causing 50% mortality in the test population
LD_{50}	lethal dose to 50% (a dose causing 50% mortality in the test population)
LOAEL	lowest observed adverse effect level

LOC	level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
m	metre(s)
m/sec	metre(s) per second
m^3	metre(s) cubed
mg	milligram(s)
µg	microgram(s)
mg	milligram(s)
mL	millilitre(s)
mm	millimetre(s)
MOE	margin of exposure
mv	millivolt(s)
MWHC	maximum water holding capacity
nd	no detection
nm	nanometre(s)
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OC	organic carbon
OM	organic matter
PChE	plasma cholinesterase
PCP	Pest Control Product
PDP	Pesticide Data Program (United States data)
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
PSI	pre-slaughter interval
Q_1^*	cancer potency factor
REI	restricted-entry interval
Rf	retardation factor in chromatography
RQ	risk quotient
TC	transfer coefficient
TGAI	technical grade active ingredient
TP	transformation product
TPM	triophanate-methyl
TSMP	Toxic Substances Management Policy
US	United States of America
USEPA	United States Environmental Protection Agency
USGS NAWQA	United States Geological Survey National Water-Quality Assessment Program
wk	week
°C	degree(s) Celsius

Appendix I Registered Ethametsulfuron Methyl Products as of 7 September 2006

Registration Number	Marketing Class[1]	Registrant	Product Name	Formulation Type	Guarantee (%)
21554	T	E.I. du Pont Canada Company	Ethametsulfuron Methyl Technical	Solid	98.7
21555	C		Muster Herbicide Dry Flowable 75%	Wettable granules	75
23569	C		Muster Toss-N-Go Herbicide Dry Flowable		75
23942	M		Ethametsulfuron 75DF Manufacturing		75

[1] T = Technical grade active ingredient; M = Manufacturing concentrate; C = Commercial.

Note: Discontinued products or products with a submission for discontinuation are not included.

Appendix II Registered Uses of Ethametsulfuron Methyl as of 7 September 2006[1]

Use-site Category	Sites		Weeds[2]	Maximum Application Rate (g a.i. /ha)	Supported Use?[3]
7, 13, 14 Industrial oil seed and fibre crops, terrestrial feed crops, terrestrial food crops	Canola (spring seeded)	Prairie provinces and Peace River Region of British Columbia	A	15	Y
			B	22.5	
		Southern Ontario	Wild mustard	11.25	Y
		Quebec and the Maritimes (New Brunswick, Prince			M
		Okanagan and Creston Valley areas of British Columbia	A	15	M
			B	22.5	
	Condiment mustard (Brown and Oriental varieties)	Prairie provinces and Peace River Region of British Columbia	A	15	Y
	Sunflower	Canada	A	15	M
			B	22.5	

[1] The formulation type for all supported end-use products is wettable granules. Application is made once per year by ground equipment only. No aerial application is allowed for any uses. Information on application equipment and the number of applications is based on both label use information and information provided by the registrant under DACO 5.2. Uses of tank-mix products including the prepackaged tank mixes are not presented.

[2] A = Flixweed (spring seedlings), green smartweed, hempnettle, wild mustard, stinkweed (suppression only)

B = Flixweed (spring seedlings), green smartweed, hempnettle, wild mustard, stinkweed, and redroot pigweed (suppression only)

[3] Y = Use is supported by the registrant

M = Use was added as a User Requested Minor Use Label Expansion and is supported by the registrant.

Appendix III Toxicology Profile for Ethametsulfuron Methyl

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise specified.

Study/Species/ # of animals per group	NOAEL (mg/kg bw/day)	Results/Effects
Metabolism/Toxicokinetic Studies		
Metabolism study (absorption, distribution, metabolism, excretion) Rats		**Absorption**: Appears moderate based on cumulative urinary excretion data. **Distribution**: Minimal residual tissue radioactivity (0.05–0.13% of the administered dose). **Metabolism**: Over half was excreted unchanged in the urine and feces. Two major metabolites (N-dimethyl and O-deethyl DPX-A7881) and a minor metabolite (free acid of parent) were identified in the urine and feces. The predominant route of metabolism for low dose exposure was N-dimethyl DPX-A7881 (23%) and for the high dose exposure was O-deethyl DPX-7881 (36%). **Excretion**: 93.8–100.0% excreted in the urine (approximately 51%) and feces (approximately 49%) within 72 hrs.
Acute Toxicity Studies		
Acute oral toxicity - Rats		LD_{50} > 5000 mg/kg bw **LOW TOXICITY**
Acute dermal toxicity - Rabbits		LD_{50} > 2000 mg/kg bw Clinical signs: Slight ↓ bw on the 1st day of exposure. 1 animal had severe erythema (normal by day 3). **LOW TOXICITY**
Acute inhalation study - Rats		LC_{50} > 5.7 mg/L Clinical signs: reddish ocular and nasal discharge. Slight ↓ bw during the first day postexposure. **LOW TOXICITY**
Skin irritation - Rabbits		**NON-IRRITATING**
Eye irritation - Rabbits		Unwashed eyes: slight to mild corneal opacity (resolved by day 10). Slight to mild conjunctival redness (absent by day 2). Light chemosis (absent by day 2). Washed eyes: similar results to unwashed eyes. Except, one animal had corneal epithelial changes still evident at day 21. The maximum total irritation scores were all below 25 out of 110. **MILDLY IRRITATING**
Dermal Sensitization - Guinea pigs		**NON-SENSITIZER**
Subchronic Toxicity Studies		
21-day dermal toxicity		**Waiver granted by the PMRA based on:** Low toxicity in short-term oral studies in the rat, mouse, and dog.
90-day dietary - mice	687	No evidence of adverse treatment-related toxicity

Study/Species/ # of animals per group	NOAEL (mg/kg bw/day)	Results/Effects
90-day dietary - rats	365	No evidence of adverse treatment-related toxicity
90-day dietary - Beagle dogs	382	No evidence of adverse treatment-related toxicity
1-year dietary - Beagle dogs	87	**@ 478 mg/kg bw/day**: ↓ bw (♂), ↓ bwg, ↓ food efficiency, ↓ serum sodium levels (no associated renal pathology), ↓ thyroid/parathyroid wt/bw or brain wt (♀).
Chronic Toxicity/Oncogenicity Studies		
78-wk dietary chronic oncogenicity - mice	68	**≥ 705 mg/kg bw/day**: ↓ bwg (♂), ↑ neutrophils, ↑ lymphadenopathy/plasmocytosis of lymph nodes, ↑ lymphadenopathy [lymphoid hyperplasia (mandibular lymph nodes ♀ and slight in ♂; and mesenteric lymph nodes in ♀ (not stat sign)], ↑ angiectasis (mesenteric lymph nodes)(♂), ↑ lymphoid hyperplasia (thymus - medullary)(♀)(not stat sign). **No evidence of oncogenicity**
Two-year dietary combined chronic toxicity and oncogenicity - rats	26	**@ 210/267 mg/kg bw/day**: ↓ bw and bwg in ♀. **No evidence of oncogenicity**
Reproductive and Developmental Toxicity Studies		
Two-generation reproduction (dietary) - rats	Parental NOAEL = 395 Offspring and Reproductive NOAELs ≥ 1582	**Parental**: **@ 1582 mg/kg bw/day**: ↓ bw and bwg during premating (P_1♂ +F_1♂ and ♀), ↓ bwg for entire treatment period (P_1♂), ↓ Fc (F_1♂),↓ liver wt/brain wt (P_1 ♂) **Fetal and Reproduction**: No evidence of adverse treatment-related toxicity
Developmental toxicity (gavage) - rats	Maternal and Developmental NOAELs = 1000	**Maternal effects**: **@ 4000 mg/kg bw/day**:↓ bwg and food consumption during dosing. **Developmental Effects**: **@ 4000 mg/kg bw/day**: ↑ incidence of skeletal findings (combined incidence of wavy and calloused ribs, in association with partially ossified bones in the skull, unossified hyoid, and partial/incomplete ossification of the sternebra and ribs) indicative of delayed skeletal development (exceeding historical control values). **No evidence of teratogenicity**

Study/Species/ # of animals per group	NOAEL (mg/kg bw/day)	Results/Effects
Developmental toxicity (gavage) - rabbits	Maternal and Developmental LOAELs = 250 **Issue: Severity of developmental effect**	**Maternal Effects**: **≥ 250 mg/kg bw/day**: ↑ early resorptions (ER)/litter, ↑ postimplantation loss, ↓ # live fetuses/litter. **≥ 1000 mg/kg bw/day**: ↑ abortions, ↑ liver wt/bw, ↑ abs liver wt, ↑ trichobezoar (hair balls without test material) **@ 4000 mg/kg bw/day**: ↓ food consumption (during dosing), ↓ # dams vith viable fetuses evaluated at term, ↑ mortality, ↓ and discoloured amounts of excreted fecal material in association with bloody discharges, post-mortem findings of "test material hair mixtures" filling the stomachs (strongly suggestive of problems with digestion or absorption of test material resulting in obstructed passage through the intestines). **Developmental effects**: **≥250 mg/kg bw/day**:↑ early resorptions (ER)/litter, ↑ postimplantation loss, ↓ # live fetuses/litter. **≥ 1000 mg/kg bw/day**: ↑ abortions **No evidence of teratogenicity**
Genotoxicity Studies		
Mutagenicity assay in *S. typhimurium* strains TA1535, TA97, TA98, and TA100	Negative	
In vitro unscheduled DNA synthesis assay in rat primary hepatocytes - freshly cultured hepatocytes from ♂ Crl:CD BR rats	Negative	
CHO/HPRT Assay - BH4 clone of the CHO - K1 cell line.	Negative	
Mouse bone marrow micronucleus assay	Negative	
Rat chromosomal aberration assay	Negative	

Appendix IV Toxicology Endpoints for Health Risk Assessment for Ethametsulfuron Methyl

EXPOSURE SCENARIO	DOSE (mg/kg bw/day)	ENDPOINT	STUDY	UF/SF or MOE[a]
Acute Dietary General population	There was no toxicological endpoint attributable to a single exposure for the general population.			
Acute Dietary Females 13+	LOAEL = 250	Increased early resorptions and postimplantation loss, and decreased number of pups born alive	Developmental toxicity - Rabbit	1000
		ARD = 0.25 mg/kg bw		
Chronic Dietary	NOAEL = 26	Decreased body weight and body-weight gain in female rats	2-year dietary chronic and oncogenicity study - rat	100
		ADI = 0.26 mg/kg bw/day		
Short-Term[b] Incidental Oral, Dermal[e] and Inhalation[f] Females 13+	oral LOAEL = 250	Increased early resorptions and postimplantation loss, and decreased number of pups born alive	Developmental toxicity - Rabbit	1000
Short-Term[b] Incidental Oral, Dermal[e] and Inhalation[f] General Population	oral NOAEL = 395	Decreased body-weight and body-weight gain in rats	2-generation rat reproduction study	100
Intermediate-Term[c] Dermal[e] and Inhalation[f]	oral NOAEL = 26	Decreased body weight and body-weight gain	2-year rat chronic/onco-genicity study	100
Long-Term[d] Dermal[e] and Inhalation[f]	oral NOAEL = 26	Decreased body weight and body-weight gain	2-year rat chronic/onco-genicity study	100

a UF/SF refers to total of uncertainty and/or safety factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments

b Duration of exposure is 1–30 days

c Duration of exposure is 1–6 months

d Duration of exposure is > 6 months

e Since an oral NOAEL was selected, a dermal absorption factor of 100% should be used in route-to-route extrapolation (dermal absorption data were not available for ethametsulfuron methyl)

f Since an oral NOAEL was selected, an inhalation absorption factor of 100% should be used in route-to-route extrapolation

Appendix V Occupational Exposure Risk Estimates for Ethametsulfuron Methyl

Table 1 Route Specific MOEs for Mixers/Loaders/Applicators of Products Containing Ethametsulfuron Methyl

Crop	Method of Application	Formulation[a]	Application Rate[b] (kg a.i./ha)	Area Treated (ha/day)	Daily Exposure (µg/kg/day)[c,d]		Margins of Exposure[c,d]		
					Dermal	Inhalation Without Respirator	Dermal	Inhalation Without Respirator	Combined[e]
Baseline PPE (see section 3.2.2): open M/L or closed M/L for WSP; open cab application without gloves.							**Target MOE = 1000**		
Spring Canola (Rapeseed)	Groundboom	WG	0.0225	300	18.97	0.191	13 177	1 309 390	13 046
				100	6.32	0.064	39 531	3 928 171	39 137
Spring Canola (Rapeseed) and Sunflower	Groundboom	WG in WSP	0.0225	300	4.76	0.102	52 527	2 441 236	51 421
				100	1.59	0.034	157 582	7 323 708	154 263
Mustard (Brown and Oriental)	Groundboom	WG	0.015	300	12.65	0.127	19 766	1 964 085	19 569
				100	4.22	0.042	59 297	5 892 256	58 706
Mustard (Brown and Oriental)	Groundboom	WG in WSP	0.015	300	3.17	0.068	78 791	3 661 854	77 131
				100	1.06	0.023	236 373	10 985 562	231 394

[a] WG = wettable granule, WSP = water soluble package

[b] Maximum label rate.

[c] Dermal MOE = dermal NOAEL / dermal exposure. Short-term LOAEL = 250 mg/kg bw/day . Dermal exposure (µg/kg bw/day) = (dermal unit exposure value × area treated per day × application rate × DA)/ body weight. DA (dermal absorption) = 100%, Body weight = 70kg.

[d] Inhalation MOE = inhalation NOAEL / inhalation exposure. Short-term LOAEL = 250 mg/kg bw/day. Inhalation exposure (µg/kg bw/day) = (Inhalation unit exposure value × area treated per day × application rate)/ body weight. Body weight = 70kg.

[e] Combined MOE = $1/(1/MOE_{dermal}+1/MOE_{inhalation})$

Table 2 Postapplication Exposure Estimates for Re-entry into Fields Treated with Ethametsulfuron Methyl

Activity	Crop	Foliage	Transfer Coefficient (cm^2/hr)[a]	Application Rate (kg a.i./ha)	Peak DFR ($\mu g/cm^2$)[b]	Exposure ($\mu g/kg$ bw/day)	MOE (Day 0)[d] Target = 1000
Scouting	Spring Canola (Rapeseed)	Full	1500	0.0225	0.045	7.71	32 407
		Low	100			0.51	486 111
	Sunflower	Full	1000			5.14	48 611
		Min	400			2.06	121 528
	Mustard (condiment)	Min	1500	0.015	0.03	5.14	48 611
			100			0.34	729 167

[a] Transfer coefficients(TC) are from the Science Advisory Council for Exposure, Policy No. 003.1 (USEPA, 2000b) and any amendments thereof.

[b] Dislodgeable foliar residue (DFR) calculations are based on a peak default DFR value of 20% of the application rate and a dissipation rate of 10% per day. Based on one application per season.

[c] Exposure = DFR × TC × 8 hr × DA / 70 kg. (DA = dermal absorption of 100%)

[d] Based on worker short-term oral LOAEL of 250 mg/kg bw/day and target MOE of 1000. Margin of Exposure (MOE) = NOAEL/Exposure

Appendix VI Dietary (Food and Water) Exposure and Risk Estimates for Ethametsulfuron Methyl

	Dietary (food and water) Exposure (mg/kg bw/day)		Risk Estimates	
Population	**Acute**	**Chronic**	**%ARfD**	**%ADI**
Canadian Population (total)		0.000254		0.1
All infants (< 1 year)		0.000526		0.1
Children 1–2 yrs		0.000948		0.4
Children 3–5 yrs		0.000666		0.3
Children 6–12 yrs		0.000409		0.2
Youth 13–19 yrs		0.000213		0.1
Adults 20–49 yrs		0.000176		0.1
Adults 50+ yrs		0.00017		0.1
Females 13–49 yrs	0.00039	0.000173	0.16	0.1
Reference doses	ARfD (female 13–49 years)	0.25	mg/kg bw/day	
	ADI	0.26	mg/kg bw/day	

Appendix VII Food Residue Chemistry Summary

1.1 Metabolism

The PMRA has concluded that the residue chemistry database for ethametsulfuron methyl is well documented. Conclusions from the USEPA (1997 and 2001) and the National Registration Authority for Agricultural and Veterinary Chemicals of Australia (2002) are consistent with the PMRA's conclusion.

1.1.1 Plant Metabolism

The PMRA has reviewed ethametsulfuron methyl metabolism studies conducted on two different crops including the canola (oilseed) and the rutabaga (root and tuber vegetables) and has concluded that the qualitative and quantitative metabolic fate, transposition and disposition of ethametsulfuron methyl have been adequately demonstrated. Metabolism in plants involved the dealkylation of the oxygen and nitrogen substituents at the triazine moiety to yield O-deethylated ethametsulfuron methyl and its degradation product N-demethylated O-deethylated ethametsulfuron methyl. The major metabolite O-deethyl ethametsulfuron methyl is a poor inhibitor of acetolactate synthase and is herbicidally inactive in whole plant studies. The PMRA has previously concluded that for future use expansions to crops other than roots and oilseeds, additional metabolism studies will be required to elucidate the metabolic profile of ethametsulfuron methyl in plants.

1.1.2 Animal Metabolism

Metabolism studies on rats showed a rapid and extensive elimination of orally administered [^{14}C] ethametsulfuron methyl. Metabolism in rats involved the dealkylation of the oxygen and nitrogen substituents at the triazine moiety to yield N-demethylated ethametsulfuron methyl and O-deethylated ethametsulfuron methyl.

1.1.3 Residue Definition

Based on metabolism studies which showed a rapid and extensive metabolism of and given the similarity in metabolic profile, the residue definition (RD) is the parent compound. This definition is consistent with that of the USEPA and the NRA. Since no significant residues are expected to be present in feed products intended for livestock consumption, the PMRA has concluded there is no need to propose a definition of residue for food of animal origin.

1.2 Analytical Methodology

1.2.1 Methods for Residue Analysis of Plants and Plant Products

The PMRA has reviewed analytical methods used for the analysis of ethametsulfuron methyl in rutabaga, canola/sunflower and mustard. The methodology used is a High Performance Liquid Chromatography coupled with Ultraviolet detector (HPLC-UV), a High Performance Liquid Chromatography coupled with photoconductivity detector and Liquid Chromatography coupled

with Mass Spectroscopy. Residues of ethametsulfuron methyl in canola processed fractions, including pressed cake, desolventized meal, crude oil, pressed oil, solvent extracted oil, degummed oil, refined washed oil, refined bleached oil and deodorized oil were determined by HPLC. The methods were considered acceptable for data gathering. An LC-MS method capable of determining residues of ethametsulfuron methyl in canola seed was reviewed and found valid for data gathering. As well, this method is considered acceptable as a data gathering method for residues of ethametsulfuron methyl in sunflower seed.

1.2.2 Methods for Residue Analysis of Food of Animal Origin

An analytical method for food of animal origin is not required (see Section 1.3.3).

1.2.3 Multiresidue Methodology

The multiresidue method for fruits and vegetables of the CFIA does not list ethametsulfuron methyl as one of the pesticides that has been evaluated through the MRM protocols. As well, none of the United States Food and Drug Administration multiresidue protocols (A to E) are applicable for the analysis of ethametsulfuron methyl.

1.3 Food Residues

1.3.1 Freezer Storage Stability

The PMRA has reviewed a freezer storage stability study for rapeseed in which canola samples were spiked with 0.1 ppm of ethametsulfuron methyl. Samples were analyzed at time 0 and then after 1, 12 and 18 months of storage under frozen conditions. The results indicated that residues of the parent compound remained stable for up to 18 months. Also, the PMRA has reviewed a storage stability study conducted in 2005 for determination of ethametsulfuron methyl residues extracted from sunflower and has concluded that results of this study were similar to those observed in canola. Residues of ethametsulfuron methyl were below the LOQ (0.02 ppm).

1.3.2 Crop Residues

The PMRA has reviewed supervised residue trial studies conducted for mustard seed, rapeseed/sunflower and rutabagas. Data clearly showed that no quantifiable ethametsulfuron methyl residues were detected. These results are consistent with those conducted in Australia.

1.3.3 Livestock Residues

Based on the residue data available for the registered uses of ethametsulfuron methyl on feed and food crops, there is no expectation that secondary residues will occur in livestock matrices (i.e. meat and meat byproducts, milk and/or eggs) as a result of feeding treated list crop commodities or their by-products when the pesticide is used according to GAP. Consequently, MRLs will not be established in meat, milk and/or eggs at this time. As there is no expectation of dietary exposure to ethametsulfuron methyl via livestock commodities, there is no anticipated additional human exposure from consumption of foods of animal origin.

1.3.4 Confined Accumulation in Rotational Crops

Due to the persistent nature of ethametsulfuron methyl, minimum crop rotation intervals must be respected to avoid residual activity and possible phytotoxicity to susceptible rotational crops. Studies conducted using ^{14}C radiolabelled phenyl and triazine indicated that the Total Radioactive Residues (TRR) were low in flax seed and straw, cabbage and sugar beet tops. As TRR were lower than 0.1 ppm, no characterization or identification was conducted for these crops. However, significant residues were detected in wheat chaff and straw (0.053–0.561 ppm for a 120-day aging period and 0.054–0.140 ppm for a 10-month aging period) with much lower residues detected in wheat grain (0.012–0.02 ppm) for both aging periods. Radioactivity was associated with primarily N-demethyl triazine amine and O-deethyl triazine amine. Unextracted and unidentified fractions also contained significant amounts of radioactivity. Rotational crop studies have been performed in the prairies to develop guidelines which outline the "waiting" period for major rotational crops (refer to Table 1). For all other rotational crops a field test strip must be made 22 months after the application date.

Table 1 Interval prior to planting rotational crops

Interval (months after application)	Crops
10	Spring wheat Durum wheat Barley Oats Flax
22	Canola Lentils Peas Faba beans Tame mustard Dry beans Alfalfa Fescue Red clover

Appendix VIII Water Monitoring Data

A search for ethametsulfuron methyl water monitoring data in Canada revealed that routine analysis for ethametsulfuron methyl is not conducted. Members of the Federal-Provincial-Territorial committee on Pest Management and Pesticides were contacted, requesting existing water monitoring data for the sulfonyl-ureas that are currently under re-evaluation. Requests for existing data were also submitted to Environment Canada, the Department of Fisheries and Oceans and the drinking water subcommittee through Health Canada. Ethametsulfuron methyl was detected in two drinking water reservoirs in Alberta, one in Saskatchewan and three in Manitoba at maximum concentrations of 0.32, 12.15 and 80.42 ng/L/province, respectively. Two dugouts that were known drinking water sources were sampled and one of these dugouts had ethametsulfuron methyl detections at a detection frequency of 100% and a maximum concentration of 5.96 ng/L. Ethametsulfuron methyl was also detected in two prairie rivers at maximum concentrations of 8.13 and 2.31, respectively, in four creeks at maximum concentrations ranging from 1.74 to 3.88 ng/L, and in two wetlands at maximum concentrations ranging from 1.17 to 1.26 ng/L.

The monitoring data likely underestimate the peak exposure for ethametsulfuron methyl because of the following sources of uncertainty:

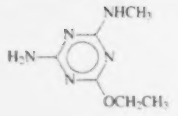
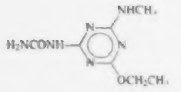
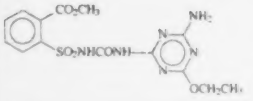
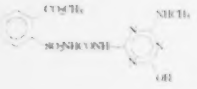
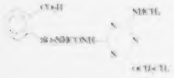
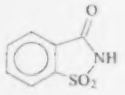
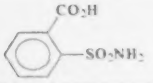
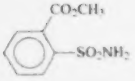
- Sampling in some of the studies was conducted during periods when ethametsulfuron methyl was not applied in Canada (i.e. October through March).
- Samples are often taken at arbitrary time intervals (i.e. once a month, once a week) and are unlikely to capture the absolute maximum concentration of ethametsulfuron methyl;
- Ethametsulfuron methyl use information from the areas surrounding where the samples were collected were not available.
- The concentrations of mobile pesticides in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and runoff events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections.

A review of the available water monitoring data revealed that details on the application of ethametsulfuron methyl were not available. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects were a result of non-transport or more simply a result of the timing of sampling. In addition, the maximum concentration recorded may not be the absolute maximum concentration that would be observed in Canada. Factors that may result in higher concentrations being detected include application at higher rates, precipitation and some areas/soils are simply more prone to leaching and/or run-off. Sampling at intervals immediately following application would increase the likelihood that the maximum concentration would be detected.

The scarcity of monitoring data in Canada and the lack of such data in United States does not allow for an estimation of the residues of ethametsulfuron methyl in potential drinking water sources to be calculated through statistical analysis of monitoring data. The analysis of ethametsulfuron methyl in Canadian waters has only been recently done due to analytical methodology limitations. The drinking water values currently available for use in the PMRA aggregate dietary risk assessment are those determined by the Level 1 water models.

In view of the uncertainty caused by the above factors, the limited water monitoring data were not used in the environmental risk assessment.

Appendix IX Major Transformation Products of Ethametsulfuron Methyl

DuPont Code	Chemical Name	Common Name	Chemical Structure
IN-A4098, D7556-4 or IN D7556-4	6-Ethoxy-N-methyl-1, 3, 5- triazine-2, 4-diamine	Triazine Amine	
B9161 or INB9161	[4-Ethoxy-6-(methyl-amine)-1, 3, 5-triazin-2-yl] urea	Triazine Urea	
N-Demethyl DPX-A7881	Methyl 2-[[[[(4-amino-6-ethoxy-1, 3, 5-triazin-2-yl) amino]carbonyl]-amino]sulfonyl]benzoate	–Demethyl Ethametsulfuron methyl	
O-Deethyl DPX-A7881	Methyl 2-[[[[(4-hydroxy-6-(methylamino)-1, 3, 5-triazin-2-yl) amino]carbonyl]-amino]sulfonyl]benzoate	O-Deethyl Ethametsulfuron methyl	
DPX-A7881 acid	2[[[[4-ethoxy-6-(methylamino)-1, 3, 5-triazin-2-yl]-amino]carbonyl] amino]sulfonyl]benzoic acid	Ethametsulfuron methyl acid	
—	1,2-Benzisothiazol-3 (2H)- one, 1,1-dioxide	Saccharin	
—	2-(aminosulfonyl) benzoic acid	Acid sulfonamide	
—	Methyl 2- (aminosulfonyl)-benzoate	Ester Sulfonamide	

Appendix X Environmental Fate and Toxicity

Table 1 Environmental Fate of Ethametsulfuron Methyl and its Transformation Products

Study Type	Test Material	Study Conditions	Value or Endpoint	Interpretation	Major Transformation Products
Abiotic Transformation					
Hydrolysis	Ethametsulfuron methyl	30 d	25°C / 45°C pH 5: 41–45 d / — pH 7: > 32 d / — pH 8: — / 29 d pH 9: > 32 d / 29 d pH 12: — / 0.5 d	Not a major route of transformation at low temperature and at neutral and basic conditions	Triazine amine, saccharin and ester sulfonamide.
Phototransformation soil	Ethametsulfuron methyl	Alberta black loam	pH 5.6, > 120 d	Not a major route of transformation	Saccharin
Phototransformation water	Ethametsulfuron methyl	30 d	pH 7, 25°C > 150 d	Not a major route of transformation	Major transformation products were not formed (i.e. >10% of applied a.r.)
Biotransformation					
Soil - aerobic	Ethametsulfuron methyl	8 soils Sandy loam to clay loam, pH 5.6–7.8, % OM 2.3–19	Half-life: 17.6–236 d	Slightly persistent to Persistent	Not determined
		365 d. Loam, pH 5.6, 70% NMHC, 25°C 365 d. Loam, pH 5.6, 70% NMHC, 5°C 365 d. Loam, pH 5.6, 13% NMHC, 25°C 365 d. Loam, pH 5.6, 13% NMHC, 5°C	DT_{50} 63, 75 d DT_{50} 300 d DT_{50} 90 d DT_{50} 570 d	Moderately persistent Persistent Moderately persistent Persistent	Triazine amine
		20 weeks, US silt loam, pH 6.4; % OM 2.8; temperature not reported	DT_{50} < 1.0 d	Non-persistent	Saccharin

Study Type	Test Material	Study Conditions	Value or Endpoint	Interpretation	Major Transformation Products
Water/sediment - aerobic	Ethametsulfuron methyl	Two systems: 365 d, pH 8, 5°C–29°C	5°C, half-life: 2595–3390 d 29°C, half-life: 180–192 d	Persistent Persistent	Triazine amine, N-demethyl triazine amine, Saccharin
Water/sediment-anaerobic	Ethametsulfuron methyl	365 d; 25°C; pH 5.6–9.3	Non-sterile half-life: 62–272 d Sterile half-life: 155–540 d	Persistent to moderately persistent Persistent	Triazine amine, Ethametsulfuron methyl acid
Mobility					
Adsorption/ desorption	Ethametsulfuron methyl	Four soils: 25°C; pH 4.3–6.6; % OM 1.1–4.7	K_d 0.53–4.06 K_{oc} 82–149	Highly mobile	Not determined
Soil column leaching	Ethametsulfuron methyl	Four soils (pH 5.8–7.4; % OM 1.0–10.3), non-aged and aged (30 days)	High percent retained on soil K_d = 1.82 - K_{oc} = 30.5 K_d = 0.80 - K_{oc} = 125 K_d = 0.27 - K_{oc} = 46.6	Low mobility Moderate to very high mobility High mobility Very high mobility	Saccharin and Triazine amine
	Saccharin	Loam, pH 5.8, % OM 7.6	K_d = 0.24 - K_{oc} = 5.44	Very high mobility	
	Triazine amine	Loam, pH 5.8, % OM 7.6	High percent retained on soil	Low mobility	
Soil thin layer chromatography	Ethametsulfuron methyl	Four soils: sandy loam and silt loam, pH 4.3–6.6, % OM 1.1–4.7	Rf = 0.07–0.64	Immobile to intermediate mobility	Not reported
	Ethametsulfuron methyl	Four soils: sandy loam and silt loam, pH 4.3–6.6, % OM 1.1–4.7	Rf = 0.11–0.51	Low to intermediate mobility	Saccharin and triazine amine
	Saccharin	Four soils: sandy loam and silt loam, pH 4.3–6.6, % OM 1.1–4.7	Rf = 0.74–0.83	Very mobile	—

Study Type	Test Material	Study Conditions	Value or Endpoint	Interpretation	Major Transformation Products
	Triazine amine	Four soils: sandy loam and silt loam, pH 4.3–6.6, % OM 1.1–4.7	Rf = 0.13–0.19	Immobile to low mobility	—
Field Studies					
Field dissipation	Ethametsulfuron methyl	Four Canadian sites: Alberta(2), Saskatchewan, Manitoba pH range: 6.1–7.9	DT_{50} = 45–160 d	Moderately persistent; Evidence that leaching may have occurred beyond 22,5 cm depth at one site.	Saccharin, Ester sulfonamide, triazin urea and triazine amine.

* Soil moisture at field capacity

Table 2 Environmental Toxicity of Ethametsulfuron Methyl and its Transformation Products

Organism	Study Type	Species	Test Material	Endpoint	Value (effect)	Effect of Concern
Terrestrial Species						
Invertebrate	Acute contact	Honeybee (*Apis mellifera*)	Technical	48-h LD_{50}	> 12.5 µg a.i./bee	Mortality
		Earthworm (*Eisenia foetida*)		14-d LC_{50}	> 1000 mg a.i./kg soil	Mortality
Birds	Acute oral	Mallard duck (*Anas platyrhynchos*)	Technical	LD_{50}	> 2250 mg a.i./kg bw	Mortality
		Bobwhite quail (*Colinus virginianus*)			> 2250 mg a.i./kg bw	
	Dietary	Mallard duck (*Anas platyrhynchos*)	Technical	LC_{50}	5620 mg a.i./kg diet	Mortality
		Bobwhite quail (*Colinus virginianus*)			5620 mg a.i./kg diet	

Organism	Study Type		Species	Test Material	Endpoint	Value (effect)	Effect of Concern
Mammals	Acute	Oral	Rat	Technical	LD_{50}	> 5000 mg a.i./kg bw	Mortality
		Inhalation	Rat		LC_{50}	> 5.7 mg/L	
		Skin and eye	Rabbit		LD_{50}	> 2200 mg a.i./kg bw/day	
	Short term	Dietary 14-days	Rat	Technical	NOEL	2200 mg a.i./kg bw/day	Mortality
		Dietary 90-days	Rat		NOEL	90 mg a.i./kg bw/day	
			Mouse		NOEL	800 mg a.i./kg bw/day	
	Long term	Dietary 2-years	Rat	Technical	NOEL	210–238 mg a.i./kg bw/day	Decreased body weight
		Dietary 20-months	Mouse		NOEL	705–930 mg a.i./kg bw/day	Increased lymphadenopathy/plasmocytosis of lymph nodes
		2-generation	Rat (parental)		NOEL	395 mg a.i./kg bw/day	Decreased body weight
			Rat (offspring)		NOEL	1582 mg a.i./kg bw/day	
		Foetal development	Rat		NOAEL	1000 mg a.i./kg bw/day	Delayed ossification
		Maternal	Rabbit		LOAEL	250 mg a.i./kg bw/day	Increased liver weight
		Embriotoxicity	Rabbit		NOEL	1000 mg a.i./kg bw/day	Increased abortions

Organism	Study Type	Species	Test Material	Endpoint	Value (effect)	Effect of Concern
Terrestrial plants	Vegetative vigor	7 plant species	Formulation (75% purity)	EC_{25}	26.4 g a.i./ha	Reduced plant biomass
					25.9 g a.i./ha	Reduced seed production
	Vegetative vigour	50 plant species (greenhouse test)	Technical	EC_{25}	0.009 –39.5 g a.i./ha	Reduced recovery
		50 plant species (field test)	Formulation (75% purity)	EC_{25}	0.036–59.0 g a.i./ha	Reduced recovery
Freshwater Organisms						
Invertebrates	Acute	*Daphnia magna*	Technical	48-h LC_{50}	> 200 mg a.i./L	Immobility
				48-h LC_{50}	> 34 mg a.i./L	Immobility
				48-h LC_{50} NOEC	> 550 mg a.i./L 550 mg a.i./L	Immobility
			Triazine urea	48-h LC_{50}	> 3.0 mg a.i./L	Immobility
			Triazine amine	48-h LC_{50}	> 3.0 mg a.i./L	Immobility
	Chronic	*Daphnia magna*	Technical	21-d NOEL MATC	> 30 mg a.i./L 30–95 mg a.i./L	Decreased adult growth, number of offspring per adult

Organism	Study Type	Species	Test Material	Endpoint	Value (effect)	Effect of Concern
Fish	Acute	Rainbow trout (*Oncorhynchus mykiss*)	Technical	96-h LC_{50}	> 600 mg a.i./L	Mortality
		Bluegill sunfish (*Lepomis macrochirus*)		96-h LC_{50}	> 600 mg a.i./L	Mortality
Algae	Acute	Green algae (*Selenastrum capricornutum*)	Technical	120-h EC_{50} NOEC	2.6 mg a.i./L 0.5 µg a.i./L	Cell density, biomass and growth rate
Aquatic vascular plants	Acute	Duckweed (*Lemna minor*)	Technical	14-d EC_{50} NOEC	0.05–2.1 µg a.i./L 0.05–5.0 µg a.i./L	Frond number
		Sago pondweed (*Potamogeton pectinatus*)		14-d EC_{50} NOEC	0.0.05–1.5 µg a.i./L 0.05 µg a.i./L	Root dry weight
		Eurasian watermilfoil (*Myriophyllum spicatum*)		14-d EC_{50} NOEC	> 5.0 µg a.i./L 0.05 µg a.i./L	Root dry weight

Table 3 Summary of Screening Level Risk Assessment of Ethametsulfuron Methyl to Terrestrial Invertebrates and Plants

Organism	Exposure	Endpoint Reported	Use Rate (g a.i./ha)	EEC	RQ	Exceedance of LOC
Invertebrates						
Honeybee	Acute contact	LD_{50} > 12.5 µg a.i./bee (14 kg a.i./ha)	22.5	2.25×10^{-2} kg a.i./ha	1.6×10^{-3}	0
Earthworm		LD_{50} > 1000 mg a.i./kg soil	22.5	1.0×10^{-2} mg a.i./kg soil	1.0×10^{-5}	0
Plants						
Plants	Vegetative vigor (Green smartweed, *Polygonum lapatifolium*)	EC_{25} = 0.009 g a.i./ha	12.5	12.5 g a.i./ha	1389	1389 ×

Table 4 Summary of Screening Level Risk Assessment of Ethametsulfuron Methyl to Birds and Mammals

Organism	Exposure	Endpoint (mg a.i./kg body weight/day)	Food Guild	EDE (mg a.i./kg body weight/day)	RQ	Exceedance of LOC
Birds						
Small (20 g)	Acute Oral	225	Insectivore	1.1	5.0×10^{-3}	0
			Granivore	0.2	1.0×10^{-3}	0
			Fructivore	0.6	3.0×10^{-3}	0
	Dietary	31.8	Insectivore	1.1	3.5×10^{-2}	0
			Granivore	0.2	6.0×10^{-3}	0
			Fructivore	0.6	1.9×10^{-2}	0
Medium (100 g)	Acute Oral	225	Insectivore	0.9	1.0×10^{-3}	0
			Granivore	0.2	1.0×10^{-3}	0
			Fructivore	1.1	5.0×10^{-3}	0
	Dietary	31.8	Insectivore	0.9	2.8×10^{-2}	0
			Granivore	0.2	6.0×10^{-3}	0
			Fructivore	1.1	3.5×10^{-2}	0

Organism	Exposure	Endpoint (mg a.i./kg body weight/day)	Food Guild	EDE (mg a.i./kg body weight/day)	RQ	Exceedance of LOC
Large (1000 g)	Acute	225	Insectivore	0.2	1.0×10^{-3}	0
			Granivore	0.6	3.0×10^{-3}	0
			Fructivore	0.1	4.0×10^{-4}	0
			Herbivore	1.6	7.0×10^{-3}	0
	Dietary	31.8	Insectivore	0.2	6.0×10^{-3}	0
			Granivore	0.6	1.9×10^{-2}	0
			Fructivore	0.1	3.0×10^{-3}	0
			Herbivore	1.6	5.0×10^{-2}	0
Mammals						
Small (15 g)	Acute Oral	500	Insectivore	0.66	1.3×10^{-3}	0
			Granivore	0.12	2.0×10^{-4}	0
			Fructivore	0.34	7.0×10^{-4}	0
			Herbivore	4.1	8.2×10^{-3}	0
	Reproduction	250	Insectivore	0.66	3.0×10^{-3}	0
			Granivore	0.12	5.0×10^{-4}	0
			Fructivore	0.34	1.3×10^{-3}	0
			Herbivore	4.1	1.6×10^{-2}	0
Medium (35 g)	Acute Oral	500	Mnsectivore	0.58	1.1×10^{-3}	0
			Granivore	0.1	2.0×10^{-4}	0
			Fructivore	0.3	6.0×10^{-4}	0
			Herbivore	3.6	7.1×10^{-3}	0
	Reproduction	250	Insectivore	0.58	2.3×10^{-3}	0
			Granivore	0.1	4.0×10^{-4}	0
			Fructivore	0.3	1.2×10^{-3}	0
			Herbivore	3.6	1.4×10^{-2}	0

Organism	Exposure	Endpoint (mg a.i./kg body weight/day)	Food Guild	EDE (mg a.i./kg body weight/day)	RQ	Exceedance of LOC
Large (1000 g)	Acute Oral	500	Insectivore	0.31	6.0×10^{-4}	0
			Granivore	0.05	1.0×10^{-4}	0
			Fructivore	0.16	3.0×10^{-4}	0
			Herbivore	1.9	3.8×10^{-3}	0
	Reproduction	250	Insectivore	0.31	1.2×10^{-3}	0
			Granivore	0.05	2.0×10^{-4}	0
			Fructivore	0.16	6.0×10^{-4}	0
			Herbivore	1.9	7.6×10^{-3}	0

Table 5 Refined Risk Assessment of Ethametsulfuron Methyl to Terrestrial Plants

Organism	Exposure	EC_{25} g a.i./ha	Use Rate (g a.i./ha)	% Application Rate to Reach EC_{25}	Drift EEC* (g a.i./ha)	RQ	Exceedance of LOC
Plants	Vegetative vigor (Green smartweed, *Polygonum lapatifolium*)	0.009	12.5	0.07	0.75	83.3	83 ×
			15	0.06	0.9	100	100 ×
			22.5	0.04	0.90–1.35	150	150 ×

Based on drift of 6% for a default droplet size of medium (herbicides).

Table 6 Summary of Screening Level Risk Assessment of Ethametsulfuron Methyl to Aquatic Organisms

Organism	Exposure	Species	Endpoint Reported (mg a.i./L)	Endpoint for RA* (mg a.i./L)	Use Rate (g a.i./ha)	EEC** (mg a.i./L)	RQ	Exceedance of LOC
Freshwater Species								
Invertebrate	Acute	*D. magna*	$LC_{50} > 34$	17	22.5	0	2.0×10^{-4}	0
	Chronic	*D. magna*	NOEL = 30	15	22.5	0	2.0×10^{-4}	0
Fish	Acute	Rainbow trout (*Onchorhynchus mykiss*)	$LC_{50} > 600$	60	22.5	0.0028	5.0×10^{-5}	0
Algae		Green algae (*Selenastrum capricornutum*)	$EC_{50} > 2.6$	1.3	22.5	0.0028	2.0×10^{-3}	0
Vascular Plant	Acute	Sago pondweed (Potamogeton *pectinatus*)	EC_{50} = 0.00005	0	12.5	0.0016	64	64 ×
Amphibian	Acute	Rainbow trout (surrogate)	$LC_{50} > 600$	60	22.5	0.0083	1.0×10^{-4}	0

* Endpoints used in the acute exposure risk assessment (RA) are derived by dividing the EC_{50} or LC_{50} from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates and plants, and by a factor of ten (10) for fish and amphibians.

** EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

Table 7 Summary of Screening Level Risk Assessment of Ethametsulfuron Methyl Transformation Products to Aquatic Organisms

Organism	Exposure	Species	Endpoint Reported (mg a.i./L)	Endpoint for RA* (mg a.i./L)	Use Rate (g a.i./ha)	EEC** (mg a.i./L)	RQ	Exceedance of LOC
Triazine amine								
Invertebrate	Acute	*D. magna*	$LC_{50} > 3.0$	1.5	22.5	0.001	6.0×10^{-4}	0

* Endpoints used in the acute exposure risk assessment (RA) are derived by dividing the EC_{50} or LC_{50} from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates.

Table 8 Refined Risk Assessment of Ethametsulfuron Methyl to Aquatic Organisms From Spray Drift

Organism	Exposure	$EC_{50} \div 2$* (µg a.i./L)	Use Rate (g a.i./ha)	Drift EEC** (µg a.i./L)	RQ	Exceedance of LOC
Plants	Acute	0.025	12.5	0.09	3.6	3.6 ×
			15	0.1	4	4 ×
			22.5	0.2	8	8 ×

* Endpoints used in the acute exposure risk assessment for aquatic plants are derived by dividing the EC_{50} from the appropriate laboratory study by a factor of two (2).

** Based on drift of 6% for a default droplet size of medium (herbicides).

Table 9 Risk Assessment of Ethametsulfuron Methyl for Freshwater Organisms From Predicted Run-off

Endpoint [µg a.i./L]	Use Rate (g a.i./ha)	EEC [µg a.i./L]*	RQ	Exceedance of LOC
Vascular plants				
0.025	22.5	1.72	68.8	68.8 ×

* 90th percentile of 21d average runoff values. This time frame was chosen because it most closely matches the 14-day exposure time used to generate the endpoint for the most sensitive aquatic plant, Sago pondweed *(Potamogeton pectinatus)*.

Appendix XI Label Amendments for Commercial Class Products Containing Ethametsulfuron Methyl

Canadian commercial end-use product labels must be amended to include the following statements to further protect workers and the environment.

FOR ALL FORMULATIONS:

Add to **DIRECTIONS FOR USE:**

- Do not re-enter treated fields until 12 hours after application.
- Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings.

Field sprayer application:

- **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty.
- **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. The best available application strategies which minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

  Buffer zones:
  The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrub lands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and marine/estuarine habitats.

Application rate (and use)*	Buffer Zones (metres) Required for the Protection of:		
	Freshwater and Marine/Estuarine Habitat of Depths:		Terrestrial habitat
	0.8 m	> 1 m	
12.5 g a.i./ha (Sunflower)*	3	1	34
15 g a.i./ha (Condiment mustard)	3	2	40
15–22.5 g a.i./ha (Canola)	4	2	56

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Add to **PRECAUTIONS:**

- Wear long-sleeved shirt, long pants, socks, and chemical-resistant gloves and footwear during mixing, loading, application, clean-up and repair. Chemical-resistant gloves are not required while operating groundboom sprayers.

Add to **DISPOSAL**

Disposal statements should be in compliance with the PMRA Directive, DIR 99-04 *Disposal Statements for Control Product Labels.*

Add to **ENVIRONMENTAL HAZARDS:**

TOXIC to aquatic organisms and non target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

Runoff

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine textured such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

- **Leaching**

  The use of this chemical may result in contamination of groundwater, particularly in areas where soil pH > 7, are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

FOR WETTABLE GRANULE FORMULATIONS:

Add to **DIRECTIONS FOR USE:**

- Drop intact WSP directly into spray tank. The WSP and pesticide will dissolve readily in water.
- Do not allow the WSP to become wet prior to use. Do not handle individual WSP with wet hands or wet gloves as this may cause breakage. Do not remove WSP from over-wrap container except for immediate use.
- Do not open WSP or attempt to remove the contents from them. The contents are not designed to be re-measured or subdivided.
- Do not use opened or punctured WSP.
- If broken WSP is found when the over-wrap bag is opened, avoid contact with, and inhalation of the product. Handle with chemical-resistant gloves and dispose of broken WSP according to the DISPOSAL section.

Appendix XII Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Maximum Residue Limits (MRLs) for ethametsulfuron methyl residues resulting from Canadian label uses on canola, sunflower and mustard seeds are proposed in PMRL 2006-01, while general regulation B.15.002(1) applies to all foods where a specific MRL has not been established. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 1 MRLs in Canada and Other Jurisdictions

Commodity	MRL or Tolerance (ppm)		
	Canada[1]	United States[2]	Codex
Canola	0.02	0.02	None
Mustard	0.05	Not registered	None
Sunflower	0.02	Not registered	None
Crambe	Not registered	0.02	None

Notes

1 Proposed in PMRL 2006-01. Where no MRL is specified residues are regulated to not exceed 0.1 ppm by virtue of the Food and Drugs Regulations, B.15.002(1).

2 As per Title 40 Part 180.563 of the United States Code of Federal Regulations..
See also www.access.gpo.gov/nara/cfr/waisidx_01/40cfr180_01.html

Table 2 Residue Definition in Canada and Other Jurisdictions

Jurisdiction	Residue Definition
Canada	methyl 2-[[[[[4-ethoxy-6-(methylamino)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]benzoate
United States	methyl 2- ((((4-ethoxy-6- (methylamino)-1,3,5- triazin-2-yl) amino) carbonyl) amino) sulfonyl) benzoate
Codex	None